DEPARTMENT OF HEALTH AND HUMAN SERVICES

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Food and Drug Administration
New Orleans District
Nashville Branch Office
297 Plus Park Blvd.
Nashville, TN 37217

Telephone: 615-781-5380
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August 25, 2004

Warning Letter No. 2004-NOL-34

FEDERAL EXPRESS
OVERNIGHT DELIVERY

Timothy M. Allgyer
Co-Owner
Guaranteed Total Vending
dba Creations Sandwich Company
1607 Getwell Road
Memphis, Tennessee 38111

Dear Mr. Allgyer:

On May 20-21, 2004, the Food and Drug Administration (FDA) conducted an inspection of your facility located at 1607 Getwell Road, Memphis, Tennessee. Our investigator documented several deviations from regulatory requirements, which were listed on a Form FDA 483 issued to Mr. J. Todd Pitts, Manager, on May 21, 2004. A photocopy of this document is enclosed for your review. We found you have serious deviations from the seafood Hazard Analysis Critical Control Point (HACCP) regulations, Title 21, *Code of Federal Regulations*, Part 123 (21 CFR 123). These same deviations were brought to your attention in our previous letter to you dated October 3, 2003.

In accordance with 21 CFR 123.6(g), failure of a processor to have and implement a HACCP plan that complies with this section whenever a HACCP plan is necessary, or to otherwise operate in accordance with the requirements of this part, renders the seafood products adulterated within the meaning of Section 402(a)(4) of the Federal Food, Drug, and Cosmetic Act (the Act), 21 U.S.C. § 342(a)(4). Accordingly, your tuna salad and fish patty sandwich products are adulterated because they have been prepared, packed or held under insanitary conditions whereby they may have been rendered injurious to health. You may find the Act and the seafood HACCP regulation through links in FDA's homepage at www.fda.gov.

The seafood deviations are as follows:

- You must conduct, or have conducted for you, a hazard analysis to determine whether there are food safety hazards reasonably likely to occur for each kind of fish and fishery product that you process, and you must have and implement a written HACCP plan for each identified food safety

hazard to comply with 21 CFR 123.6(a) and (b). However, your firm does not have a HACCP plan for tuna salad or fish patty sandwiches to control the food safety hazards of pathogen growth and scombrotoxin formation.

- You must monitor the sanitation conditions and practices during processing with sufficient frequency to comply with 21 CFR 123.11(b). In addition, you must maintain sanitation control records documenting your sanitation monitoring activities to comply with 21 CFR 123.11(c).

Furthermore, a review of some of your product labels reveals deviations from food labeling requirements. These deviations cause your products to be misbranded within the meaning of Section 403(i)(2) of the Act, because the labels on several of your products including, but not limited to, pimento cheese, egg salad and various sandwiches, fail to list the common or usual names of all ingredients. For example, the bread, cheese, dressing, "mayo", and relish are all ingredients composed of two or more ingredients which, unless exempt (e.g. See 21 CFR 101.100), must be declared on the label (21 CFR 101.4(b)).

Some of the ingredients not listed on your labels may be allergens or cause reactions in individuals who are sensitive to the ingredients. FDA has received increasing numbers of reports concerning consumers who have experienced adverse reactions following exposure to allergenic substances in food. For sensitive individuals, the presence of allergens in food is potentially life threatening. Ingredients among the most commonly known to cause serious allergic response are milk, eggs, fish, crustaceans, tree nuts, wheat, peanuts, soybeans and derivatives of these products.

Lastly, the name and place of business of the manufacturer, packer or distributor, must be declared on packaged foods including, but not limited to, pimento cheese, egg salad and various sandwiches, as required by 21 CFR 101.5. Specifically, your labels must declare the city, state and zip code of business.

The above noted observations are not intended to be an all-inclusive list of existing deficiencies. It is your responsibility to assure compliance with all requirements of the Act and regulations, including the violations that are listed above. You should take prompt action to correct these violations. Failure to do so may result in regulatory action without further notice; such action may include seizure and/or injunction.

You should notify this office in writing, within fifteen (15) working days of the receipt of this letter, of the specific steps you have taken to correct the noted violations, including an explanation of each step being taken to prevent the recurrence of similar violations. If corrective action cannot be completed within fifteen (15) working days, state the reason for the delay and the time within which the corrections will be completed. Please respond directly to Kari L. Batey, Compliance Officer, Food and Drug Administration, 297 Plus Park Boulevard, Nashville, Tennessee 37217 or telephone (615) 781-5380, extension 112.

Sincerely,

Patricia K. Murphy for

H. Tyler Thornburg
District Director, New Orleans District